Remarks

This Amendment is responsive to the Office Action mailed June 29, 2000 (Paper No. 9). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 25-47 were pending. Claims 25-47 stand or stood rejected.

Claim 36 has been canceled without prejudice or disclaimer of the subject matter therein. Moreover, Applicants reserve the right to prosecute, in one or more patent applications, the canceled claims, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification.

Claims 25, 33, 37, 39, 42, 44 and 47 have been amended to more particularly and distinctly define the invention. No new matter is added.

It is believed that entry of this Amendment will not require payment of any additional claim fees. Notwithstanding, Applicants hereby authorize the Commissioner to charge any additional claim fees required by entry of this Amendment to Deposit Account No. 50-0258.

Support

Support for the amendments to the claims is either apparent or as set forth herein. Specifically, support for the recitation "wherein the first polynucleotide sequence detects *Streptococcus pneumoniae*" may be found in the specification at, for example, page 17, lines 13-25. No new matter is added.

Claim Rejections under 35 U.S.C. § 101

Claims 25-47 stand or stood rejected under 35 U.S.C. § 101 as lacking patentable utility. Specifically, the Examiner asserts that

> [t]he claims are drawn to an isolated polynucleotide comprising a first polynucleotide or the full complement of the entire length of thefirst polynucleotide sequence wherein the first polynucleotide sequence is at least 95% identical to SEQ ID NO:1 (Claims 25-32 & 34-38), methods for producing the polynucleotide (Claim 33) an isolated polynucleotide encoding a polypeptide of SEQ ID NO:2

(Claims 39-41 & 44-46) and methods for producing the polypeptide (Claims 42 & 47). However, the specification fails to teach a specific utility for the claimed polynucleotide because the function of the polynucleotide or the encoded peptide is not known. The specification teaches the claimed polynucleotide sequences were identified in a DNA library derived from *Streptococcus pneumoniae* 0100993 (page 10, lines 19-20). However, the specification teaches that the polynucleotides may be obtained from other organisms (page 11, lines 27-30) and therefore, the polynucleotides are not *Streptococcus pneumoniae*-specific. The specification suggests that the peptides encoded by the claimed sequences have functions similar to the proteins of the malonyl-CoA:ACP family because polynucleotides encode a peptide having structural similarities to proteins of the malonyl-CoA:ACP family (page 10, lines 27-29). However, the specification does not teach a function for the peptides encoded by the claimed sequences wherein the teaching of a function would include demonstration of the function (e.g. assays or experimental results). Neither the specification nor the prior art teach a specific utility for the claimed invention. Hence, the claimed polynucleotide and amino acid sequences lack specific utility. Add therefore, the claimed methods are not supported by a substantial utility. The specification fails to assert any substantial utility for thepolynucleotide and amino acid sequences and methods and neither the specification as filed nor any art of record discloses or suggests any utility such that a substantial utility would be established for the sequences and methods. The teaching of a substantial utility would include a real-world use e.g. a polynucleotide or amino acid sequence having a known function wherein expression inhibits or promotes a disease and wherein the method to detect the sequence is diagnostic for the disease. Additionally, the substantial teaching would include a demonstration of the real world use e.g. experimental results. The specification teaches that the claimed sequences may be used in diagnostic assays wherein detection of the sequences will provide a diagnostic method for diagnosis of a disease (page 16, lines 12-14), for the presence of an infection (page 17, lines 20-22) and for the stage of infection and type of infection (page 14, lines 4-6). However, the sequences are not *Streptococcus pneumoniae*-specific (page 11, lines 27-30) and therefore, the specification does not teach a disease or infection for which the sequences may be diagnostic and the specification does not teach experimental results demonstrating the diagnosis. The specification teaches the sequences may be used to produce antibodies (page 17, lines 27-31) and the specification teaches antibodies may be used to

> identify the polypeptides encoded by the sequences (page 18, lines 19-20). However, the specification does not teach a substantial utility for the anti-polypeptide antibodies (e.g. diagnostics) beyond the obvious detection of the polypeptide itself. The specification teaches the claimed sequences may have utility in the discovery of antibacterial compounds for treatment or inhibition of diseases (page 21, lines 9-10 and 26-27). However, the specification does not teach any antibacterial compounds discovered by using the claimed sequences. The specification teaches the claimed sequences may be used as an antigen for inducing an immunological response (page 22, lines 8-23) and for vaccine production (page 23, lines 22-27). However, the specification does not teach experimental results which demonstrate that the antigens produce an immunological response or have utility as vaccines. The specification does not teach any specific utility nor does the specification teach any substantial utility. Therefore the suggested uses for the claimed sequences are merely means to study the properties of itself. Hence, the specification fails to support a substantial utility for the claimed methods. Because the claimed methods are not supported by a specific or substantial utility that is either well known in the art or supported by the specification, the claimed methods are not supported by a well-established utility.l The specification and the prior art fail to support a specific and substantial or well established utility for the claimed methods.

Applicants respectfully traverse. Without conceding the validity of any of the assertions made in the Examiner's rejection, Applicants note that the subject specification discloses multiple uses for the claimed polynucleotides and polypeptides. Only one such utility is required to satisfy the requirements of section 101. Particularly, the claimed polynucleotides and polypeptides are disclosed to have utility as diagnostic reagents for use in the detection of *Streptococcus pneumoniae* (a **pathogen**) in, for example, human tissue. (See specification page 17, lines 13-25). Applicants respectfully submit that the disclosed utility of the claimed polynucleotides and polypeptides as diagnostic reagents for the detection of *Streptococcus pneumoniae* is a specific and substantial utility which is credible. Abstractly, one might assert--for the sake of argument--that the claimed polynucleotides could identify bacteria other than *Streptococcus pneumoniae*, or outside the genus of Streptococcus. But, nevertheless, the claimed polynucleotides will identify bacterial contamination when present in, for example, human tissue. Whether the bacteria is of *Streptococcus pneumoniae* or not, its presence indicates pathogenicity. Moreover, the scope of the diagnostic specificity is readily determined with quintessentially ordinary experimentation.

The Examiner should note that bacteriological tests are traditionally indicative, not dispositive of the identity of a given microbe. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 25-47 stand or stood rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse. Applicant respectfully directs the Examiner's attention to the disclosure at page 19, lines 10-24 which provides:

> Polynucleotides of the present invention which encode the polypeptide of Figure 2 [SEQ ID NO:2 and 4] may include, but are not limited to the coding sequence for the mature polypeptide, by itself; the coding sequence for the mature polypeptide and additional coding sequences, such as those encoding a leader or secretory sequence, such as a pre-, or pro- or prepro- protein sequence; the coding sequence of the mature polypeptide, with or without the aforementioned additional coding sequences, together with additional, non-coding sequences, including for example, but not limited to non-coding 5' and 3' sequences, such as the transcribed, non-translated sequences that play a role in transcription (including termination signals, for example), ribosome binding, mRNA stability elements, and additional coding sequence which encode additional amino acids, such as those which provide additional functionalities. Thus, for instance, the polypeptide may be fused to a marker sequence, such as a peptide, which facilitates purification of the fused polypeptide. In certain embodiments of this aspect of the invention, the marker sequence is a hexa-histidine peptide, such as the tag provided in the pQE vector (Qiagen, Inc.), among others, many of which are commercially available. As described in Gentz *et al.*, *Proc. Natl. Acad. Sci., USA 86:* 821-824 (1989), for instance, hexa-histidine provides for convenient purification of the fusion protein. The HA tag may also be used to create fusion proteins and corresponds to an epitope derived of influenza hemagglutinin protein, which has been described by Wilson *et al.*, *Cell 37:* 767 (1984), for instance. Polynucleotides of the invention also include, but are not limited to, polynucleotides comprising a structural gene and its naturally associated genetic elements.

The Examiner further appears to assert that the application does not describe various upstream and downstream promoters, enhancers and other regulatory elements of the operon. In this regard, Applicants note that the claimed nucleic acid segments would typically be replicated in

vectors comprising the needed regulatory elements, including expression regulatory elements, if the vector is an expression vector. Such subject matter falls within what is conventional and well-known in the art; the type of sequence matter that, pursuant to the Written Description Guidelines, does not need to be disclosed in detail. Written Description Guidelines, Section II.A.3.a. Still further, the Written Description Training Materials teach as allowable claims of equivalent scope, even though the factual premises set forth in the training materials provide no further justification for claim scope relative to regulatory elements. The Office is obligated to apply its interpretation of the law consistently, and not arbitrarily. Thus, the Office cannot accept the claims of Examples 8 and 11 of the Written Description Guidelines, while rejecting Applicants' comparable claims.

Still further, Applicants note that for a written description rejection under § 112, first paragraph, to be proper, the Examiner must establish by a **preponderance** of evidence why a person skilled in the art would not recognize in the subject disclosure a description of the invention defined by the claims. *See Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. ¶1 "Written Description" Requirement; Request for Comments* (citing *Wertheim*, 541 F.2d at 262, 191 USPQ at 96). The Examiner here relies on supposition and conjecture unsupported by any evidence in rendering this rejection under § 112, first paragraph, for written description. Accordingly, the Examiner's assertion that the specification does not meet the written description provision of 35 U.S.C. § 112, first paragraph, for the full scope of the pending claims is inaccurate and falls far short of that which is required to make out a proper written description rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reexamination, reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

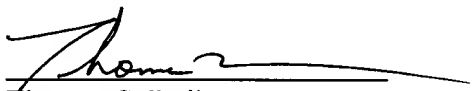
FEE DEFICIENCY

☒ If any additional extension is required, please consider this paper to comprise a petition for such an extension of time; Any fee for any extension required for consideration of this paper but not enumerated above can be charged to Account No. 50-0258.

AND/OR

☒ If any additional fee is required for consideration of this paper, please charge Account No. 50-0258.

Respectfully submitted,



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